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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,382

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EXAMINER

SHABMAN, MARK A

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,382	<b>Applicant(s)</b> LARSEN ET AL.	
	<b>Examiner</b> MARK SHABMAN	<b>Art Unit</b> 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/10/2004, 02/16/2005</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 22, 26-28** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **claim 22**, the claim recites the limitation "the deviation of the orifice diameter along a longitudinal axis of the orifice ranges from +/-1% to +/-10%". How is this deviation being measured? Is the deviation an orifice position with respect to a central axis? In this case there could be an infinite number of "longitudinal" axes as claimed throughout the orifice so an orifice can always be on a longitudinal axis or deviated from another one depending which is chosen. Is it referring to the size of the diameter of the axis? If the orifice diameter deviates 1 to 10 percent, what is it deviating from? Is the deviation along the longitudinal axis in comparison to the diameter along the lateral axis, or in comparison to a predetermined ideal diameter?

Regarding **claims 26-27**, the claims are indefinite as they all contain three possible sizes for the rounding. For example, claim 26 recites a range from 10µm to 1000µm, a range from 30µm to 75µm, and a value of approximately 50µm. In this case, a size of 15 µm falls within the first range but outside of the second and would likely not be considered "approximately equal to 50µm. A single range or size from the grouping would be more definite. The same is true for claim 27. Further, the phrase "such as"

renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding **claim 28**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

**Claims 26 and 27** recite the limitation "the rounding" in line 2 of each. There is insufficient antecedent basis for this limitation in the claim. It is assumed this is referring to the "rounded edges" of claim 23 and the claims will be examined as such.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 22 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss US Patnet 4,835,457 (hereinafter referred to as Hanss) in view of Kiesewetter US patent 4,521,729 (hereinafter referred to as Kiesewetter).

Regarding **claim 22**, Hanss discloses an apparatus for the measurement of red blood cell deformity comprising two separate chambers 2a, 2b forming a housing, each comprising a cavity 11, 12. Cavity 11 (collection chamber) is separated by cavity 12 (mixing chamber) by a membrane 5 made of plastic material or polymer (column 2 line 37). The membrane contains an "orifice" in the pores which allow particles to pass

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through from one cavity to the other (column 2 line 38). The description of the device further describes the electrodes 13, 14 as comprising a constant current through them as seen in figure 3. A change in voltage in the sensor characterizes the movement of the cells through the membrane. By spacing the electrodes apart in such a manner and keeping the current through them constant, the resulting electric field at the center of the orifice would be "homogenous" as claimed. Hanss does not disclose the "deviation of the orifice diameter along a longitudinal axis of the orifice" ranging "from +/-1% To +/- 10% as claimed.

Kiesewetter discloses an instrument for measuring the deforming capacity of red blood cells comprising an orifice or pore through which the cells travel between chambers. The pore diameter and length are said to be within a tolerance range of +/- %5. It would have been obvious to one of ordinary skill in the art at the time of invention to construct the pore or pores of Hanss in a similar manner to ensure the passageway between the two chambers is not too large or too small to allow the cells to pass through properly as is needed in common Coulter impedance testing.

Regarding **claim 29**, the apparatus of Hanss could be intended for "single use" if so desired by the user. It would have been obvious to one of ordinary skill in the art at the time of invention to create a sampling device in which the parts which were to come in contact with a blood sample were disposable to help prevent the spread of any infectious diseases contained therein to the outside of the chambers.

**Claims 23-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss in view of Kieseletter as applied to claim 22 above, and further in view of Graham US Patent 6,111,398 (hereinafter referred to as Graham).

Regarding **claim 23**, Graham discloses an apparatus for sensing and characterizing particles shown in one embodiment in figure 12 where an orifice C is seen to have rounded edges 62 as claimed. Further embodiments such as that seen in figures 10 and 11 illustrate a homogeneous electrical field at the center of the orifice as claimed. It would have been obvious to one of ordinary skill in the art at the time of invention to use the rounded edges such as those seen in Graham around the pores of Hanss as it provides improved flow properties through the conduit.

Regarding **claim 24**, Graham discloses the radius of the curvature of the rounded edges to be  $1/2$  the diameter of the orifice. As the Graham reference teaches towards rounding the orifice opening by a radius equal to one half of the diameter, it would have been obvious to one of ordinary skill in the art at the time of invention to change that amount to  $1/4$  the diameter if desired to also improve the flow properties.

Regarding **claim 25**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be as low as 0.010mm (10 $\mu$ m). At a size of 10 $\mu$ m, in order for a blood cell with an average diameter of 6 $\mu$ m to pass through, roughness on the internal surface of the orifice could at a maximum be 4 $\mu$ m which is within the range of 0-5 $\mu$ m claimed.

Regarding **claim 26**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within

a range of 10 $\mu$ m to 2000 $\mu$ m, or 30 $\mu$ m to 200 $\mu$ m for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss as these values are known in the art to be acceptable for the intended use of the invention.

Regarding **claim 27**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10 $\mu$ m to 2000 $\mu$ m, or 30 $\mu$ m to 200 $\mu$ m for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss as these values are known in the art to be acceptable for the intended use of the invention.

Regarding **claim 28**, Graham notes in column 3 line 23 that a conduit wherein the length is equal to 3/4 of the diameter is acceptable and favorable for use. If the diameter is between 10 $\mu$ m to 2000 $\mu$ m as described in line 15 of the same column, then the length would fall in the range claimed.

**Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss in view of Kieseewetter as applied to claim 22 above in further view of Berndtsson International Publication WO 99101742 (hereinafter referred to as Berndtsson).

Hanss in view of Kieseewetter discloses the claimed invention with the exception of the bore in the outer surface of the housing and the sampling member. Berndtsson discloses a disposable sampling device for particle counting apparatus comprising a housing with a bore in the outer surface 55 (figure 2, page 5 line 29) allowing for liquid

entrance into the housing, and a sampling member 52 positioned in the housing. The sampling member comprises a cavity 53 for receiving and holding a liquid sample (figures 3 and 4) and is "movably positioned as claimed. In the first position as seen in figures 2-4, the cavity is "in communication with the bore for entrance of the liquid" as claimed. In the second position as illustrated in figures 5-8, the cavity is in communication with a "mixing chamber" 61 allowing for the fluid to be discharged as seen in figure 6. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Berndtsson with those of Hanss and Kiesewetter to allow for a blood sample to enter the system directly from a donor such as the one seen in figures 3 and 4, denoted by the reference character F. This allows for faster, on site testing without the need for external syringes or pumps.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK SHABMAN whose telephone number is (571)270-3263. The examiner can normally be reached on M-F 7:30am - 5:00pm, EST (Alternating Fridays Off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. S./

Examiner, Art Unit 2856

/Hezron Williams/

Supervisory Patent Examiner, Art Unit 2856